

EXHIBIT A

Do Not Disclose - Subject to Further Confidentiality Review

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF ARIZONA

3 - - -

4 IN RE BARD IVC FILTERS : NO. MD-15-02641-PHX-DGC
5 PRODUCTS LIABILITY LITIGATION :

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9 MARCH 21, 2017

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12 CONFIDENTIALITY REVIEW

13 Videotape deposition of MARCUS

14 D'AYALA, M.D., taken pursuant to notice, was held at
15 the law offices of Aaronson Rappaport Feinstein &
16 Deutsch, LLP, 600 Third Avenue, New York, New York
17 10016, beginning at 12:45 p.m., on the above date,
18 before Amanda Dee Maslynsky-Miller, a Certified
19 Realtime Reporter and Notary Public in and for the
20 State of New York.

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1 BY MR. MATTHEWS:

2 Q. But let me ask you, then, this
3 question, just so we're clear.

4 Do you rely, in part, on IFUs, that
5 is, instructions for use, with the products you
6 implant in patients?

7 A. Yes.

8 Q. That would include --

9 A. In part.

10 Q. That would include implants, grafts,
11 stents, filters and other permanent devices?

12 A. Yes.

13 MR. MATTHEWS: All right. I would
14 like to mark as Exhibit-4 an IFU from the G2 filter
15 system that, on the last page, is dated 10/06. And
16 I presume this was the effective IFU in place at the
17 time of implant in 2007.

18 - - -

19 (Whereupon, Exhibit-4, IFU, G2 Filter
20 System, was marked for identification.)

21 - - -

22 MR. LERNER: Just so we're clear,
23 that last thing was a statement, not a question,
24 correct?

25 MR. MATTHEWS: That was a statement.

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1 have been reported without any adverse clinical
2 sequelae.

3 I'd like to ask you about the first
4 sentence: Filter fracture is a known complication
5 of vena cava filters.

6 Doctor, do you read that in the IFU
7 to mean that the rates of filter fracture are
8 similar with all filters?

9 MS. HELM: Object to the form.

10 THE WITNESS: I don't read anything
11 about rate. I read something about complications
12 and about the potential for fracture. So it makes
13 no specific statements with regards to the incidence
14 of this occurrence.

15 BY MR. MATTHEWS:

16 Q. If there is evidence that the company
17 had, in 2006 or prior to that publication being sent
18 to you with the filter, and there was a showing
19 within the company of a 500 percent greater risk
20 with Bard filter compared with other filters, is
21 that the information -- the type of information that
22 you would want to know about?

23 MS. HELM: Object to the form.

24 THE WITNESS: Yes.

25 BY MR. MATTHEWS:

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1 A. The top box?

2 Q. Yes, I messed up.

3 A. Sure. 6/21/07, vascular attending,
4 37-year-old with history of DVT PE. Uterine
5 fibroids, vaginal bleed with DVT, despite
6 anticoagulation. Awaiting surgical intervention.

7 Q. Now, it says that, Agree with need
8 for IVC filter.

9 A. Uh-huh.

10 Q. And I believe you told us that that
11 was Dr. Martin with whom you were agreeing with; is
12 that right?

13 A. Yes. Well, to read that entire box
14 it says, 37-year-old awaiting GYN surgery with
15 chronic DVT and PE. Agree with need for IVC filter.
16 Will schedule for insertion of retrievable filter
17 today. Risk/benefits discussed with patient,
18 husband, who agreed to proceed.

19 Q. And when it says, Duplex showed
20 chronic superficial DVT, is that a duplex
21 ultrasound?

22 A. Correct.

23 Q. And that's done -- how is that done?

24 A. Using ultrasound.

25 Q. All right.

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1 longer contraindicated for anticoagulants?

2 MR. MATTHEWS: Object to the form.

3 THE WITNESS: Yes.

4 BY MS. HELM:

5 Q. And as you sit here today, you don't
6 know why her filter wasn't retrieved before 2014, do
7 you?

8 A. I can only guess.

9 Q. We're not asking you to guess.

10 In 2007 when you implanted Ms.
11 Booker's G2 filter, you were aware of the potential
12 complications associated with that filter, were you
13 not?

14 MR. MATTHEWS: Object to the form.

15 THE WITNESS: Of the G2 filter?

16 BY MS. HELM:

17 Q. Yes.

18 A. The reported complications at the
19 time I was aware of, I'm sure.

20 Q. And, in fact, you previously looked
21 at Exhibit-4, which was the IFU --

22 A. Yes.

23 Q. -- for the G2 filter.

24 And you would have had that IFU
25 available to you before you implanted Ms. Booker's

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1 filter, correct?

2 A. Yes.

3 Q. And, specifically, in Section G of

4 the IFU, it discusses that one of the known

5 complications of the G2 filter is movement or

6 migration; is that right?

7 A. It does.

8 Q. And it also specifically addresses

9 that filter fracture is a known complication of vena

10 cava filters, does it not?

11 A. It does.

12 Q. And, in fact, fracture is a

13 complication of all vena cava filters, isn't it?

14 A. It is. As is migration.

15 Q. Thank you.

16 And the G2 -- and the IFU for the G2

17 filter that you implanted in Ms. Booker specifically

18 says that, There have been reports of embolization

19 of vena cava filter fragments resulting in retrieval

20 of the fragment using endovascular and/or surgical

21 techniques. Most cases a filter fracture, however,

22 have been reported without any adverse clinical

23 sequelae.

24 Is that right?

25 A. Uh-huh.

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1 Q. And so before treating Ms. Booker in
2 2007, you were aware, as you've stated, that filter
3 fracture was a risk associated with a G2 and all
4 filters; is that right?

5 A. Yes.

6 Q. And you took that into consideration
7 when weighing the risk/benefit for implanting a G2
8 filter in Ms. Booker; is that right?

9 A. Yes.

10 Q. You testified earlier that Ms.
11 Booker, because of what was going on in her medical
12 condition, was contraindicated for anticoagulants at
13 the time you inserted the filter, correct?

14 A. Yes.

15 Q. But she had a history of both PE and
16 DVT, correct?

17 A. Correct.

18 Q. And she was about to undergo surgery
19 for a cervical mass; is that right?

20 A. Right.

21 Q. And so she had to be removed from the
22 anticoagulant medication?

23 A. Right.

24 Q. But it was your -- was it your
25 understanding that post surgery that medication

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1 would be resumed, or did you have an understanding
2 of that?

3 A. I'm not entirely sure that that is
4 clear to me from the record. I can tell you that it
5 would be my practice to discuss resumption of
6 anticoagulation with all of the physicians involved
7 in her care.

8 In this particular case, it would
9 depend on no small measure as to the comfort level
10 regarding her potential for rebleeding. Keep in
11 mind, she came in anemic with a vaginal bleed and
12 she came in with DVTs and a pulmonary embolism
13 despite anticoagulation.

14 Q. Back on Page -- and I apologize, I'm
15 jumping around -- but back on Page 71 --

16 A. Sure.

17 Q. -- in your handwritten note it says,
18 Risk/benefits discussed with patient.

19 Is that right? I hope that's what it
20 says.

21 A. Yes.

22 Q. Schedule for insertion --

23 A. Yes.

24 Q. -- of retrievable filter today?

25 A. Yes. Risks/benefits discussed with

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1 patient, husband, who agreed to proceed.

2 Q. And what was your practice at the
3 time, do you recall -- at the time in 2007, what
4 risk/benefits would you have discussed with Ms.
5 Booker relating to the insertion of the retrievable
6 filter?

7 A. Right. What I would discuss with any
8 young patient regarding any implant is concerns
9 regarding durability, procedural complications. I
10 would discuss the potential for bleeding, infection;
11 a dye reaction, very unlikely, some degree of renal
12 insufficiency as the complication of the use of dye.

13 And as far as long-term
14 complications, as I stated, durability and the
15 potential for caval thrombosis, migration,
16 fragmentation. Hence, the importance for follow-up
17 and attempt at retrieval in the future.

18 Q. Was it your practice in 2007, at the
19 time you treated Ms. Booker, to inform patients that
20 the filter might have to be left permanently or --

21 A. Yes.

22 Q. -- might be there permanently?

23 And because you had identified it as
24 a retrievable filter, would you have discussed with
25 her how the retrieval of the filter would be

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1 accomplished, if that was to be done?

2 MR. MATTHEWS: Object to the form.

3 THE WITNESS: Usually, we would tell
4 them that that would be a percutaneous procedure,
5 similar to the insertion procedure, although
6 sometimes not possible.

7 BY MS. HELM:

8 Q. Did you -- was it your practice in
9 2007 to provide the plaintiff or her family member
10 with any written materials about the filter or the
11 procedure?

12 A. No.

13 Q. And would you ever give a patient a
14 copy of the IFU?

15 A. No.

16 Q. Why not?

17 A. I've never done so. It's just not my
18 practice to do so. I think that as a physician when
19 you're dealing with a patient, it's really on you to
20 make some important decisions for them. And I think
21 an IFU is a complicated document. You may correct
22 me if I'm wrong, but I think the IFU is mostly
23 intended for legal purposes. I'm not so sure it's
24 intended to guide medical practice. And I don't
25 think its intent is in any way to guide a patient in